## REMARKS

In the Office Action dated September 5, 2007, the Information Disclosure Statement filed on January 8, 2007 was stated not to comply with the provisions of 37 C.F.R. §1.98, because it did not provide a list of the references to be considered. The only "reference" that was cited in that Information Disclosure Statement was a copending application, and that copending application was cited solely out of an abundance of caution, since certain of the dependent claims in the copending application were similar to certain of the dependent claims of the present application. The cited copending application has now issued as United States Patent No. 7,266,403, and the independent claim thereof is completely unrelated to the independent claim of the present application. The issued patent concerns solely the details of the analysis unit, and has nothing whatsoever to do with a cuff of the type disclosed and claimed in the present application. Although the Examiner is certainly free to review the issued patent when the Examiner, as is required, conducts an interference search for the present application, Applicants do not view the extra expense that would be associated with re-submitting the Information Disclosure Statement as being necessary at this time, since the copending application is clearly not material to patentability of the present application under the provisions of 37 C.F.R. §1.56(a).

The Declaration was objected to because it included the phrase "material to *the* patentability" rather than the phrase "material to patentability." The undersigned representative of the Applicants is endeavoring to obtain a Substitute Declaration signed by all of the inventors that deletes the word "the" and will submit the signed Declaration as soon as it is received.

The drawings were objected to because the Examiner stated the drawings must show the cuff having a membrane. The Examiner stated in the drawings as shown, it appears that the entirety of the cuff is formed by the membrane. The Examiner also stated that the drawing should show the dosing unit in fluid communication with the flow path. In response, a revised version of Figure 1 is submitted herewith, which shows the dosing unit in fluid communication with the flow path, and which also schematically indicates the membrane as being a part of the cuff. The written portion of the specification as originally filed explicitly stated that the entirety of the outwardly facing surface of the cuff 6 is formed by the membrane 6a, but also stated that it is sufficient for only a portion of the outwardly facing surface to be formed by the membrane. In order to allow the drawing to be clarified, this written portion of the specification has been reversed.

Since all of the subject matter now shown in Figure 1 is clearly disclosed in the specification as originally filed, no new matter is added thereby.

The disclosure was objected to because of the aforementioned inconsistency between the drawing in Figure 1, which has now been corrected. This also overcomes the objection to claim 6.

Claims 1-7 were rejected under 35 U.S.C. §112, second paragraph as being indefinite because of the use of the term "specific" to modify the word "substance." Applicants believe the claim is clear simply by using the term "substance" by itself, and therefore that word "specific" has been cancelled at all locations. Claims 1-7 are therefore submitted to be in full compliance with all provisions of Section 112, second paragraph.

Claims 1-5 were rejected under 35 U.S.C. §102(b) as being anticipated by Kruse et al. Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruse et al in view of Schultze. Claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kruse et al in view of Hanson et al and further in view of Walther et al.

These rejections are respectfully traversed for the following reasons.

The subject matter disclosed and claimed in the present application is a cuff that is used in a tracheal tube, that is inserted into the trachea of a subject. As such, the cuff and the tracheal tube must obviously permit the subject to continue respirating. Applicants believe this was inherent in the language of the original claims, but claim 1 has now been amended to make this explicit.

The purpose of the cuff is to allow a substance outside of the cuff to permeate through the cuff, so as to mix with fluid in the interior of the cuff, so that the substance mixed with the fluid can be analyzed. The example provided in the specification involves surfactants that are necessary in order to allow the tracheal tube to remain comfortably inserted in the trachea. It is often the case that the patient does not naturally create enough surfactant, and since in this embodiment the cuff is permeable to the surfactant, the amount of surfactant that has permeated through the membrane of the cuff from the exterior of the cuff, so as to be mixed with the fluid in the interior of the cuff, can be monitored and. The cuff is also permeable in the opposite direction, so that if and when artificial surfactant is added, the total amount of surfactant coming into the interior of the cuff from the exterior, and the added surfactant, can continue to be analyzed.

In substantiating the anticipation rejection of claim 1 based on Kruse et al, the Examiner stated, without providing a citation to the Kruse et al reference, that the Kruse et al reference discloses a cuff that is adapted for positioning in the trachea of a subject with a patient tube. Applicants do not find any disclosure in the Kruse et al reference providing such a teaching, and in fact clearly the opposite is true in the Kruse et al reference with regard to the embodiment of Fig. 1 (which is the only embodiment that has the structure (a balloon) that the Examiner has equated with the claimed cuff). The Kruse et al reference can be inserted into a patient for placement with an organ of the patient's body, by introduction through a body orifice such as the nose, mouth or rectum (Kruse et al, column 5, lines 57-60). Even if the tube is inserted through the mouth of the patient, it is clearly not configured for placement in the trachea of the patient, because this would be fatal to the patient by completely blocking respiration. The Examiner has equated the inflatable balloon in the embodiment of Figure 1 of Kruse et al as corresponding to a "cuff," but if the device in the embodiment of Figure 1 of Kruse et al were inserted into the trachea of the patient, this would completely block respiration by the patient. The balloon is intended to be inflated, which means that the gas that is supplied to the ingress does not and cannot pass through the entirety of the tube, otherwise the balloon 14 would never become inflated. Although orifices 30 and 32 are stated to be located at the distal tip of the catheter 10, these are provided solely as safety relief orifices, and are explicitly stated not to be in communication with the vessel space 16, the egress lumen 20, or the ingress lumen 22 (Kruse et al, column 6, lines 9-19).

It is true that other embodiments are disclosed in Kruse et al, such as in Figures 2 and 3, that are provided with a membrane 132, but in those embodiments

there is no balloon present, and therefore there is no structure that could possibly be considered to correspond to a "cuff" as set forth in the claimed subject matter.

Moreover, in the Kruse et al reference the inflation of the balloon with gas, such as gas containing $CO_2$, is for the purpose of causing the gas in the interior of the balloon to reach an equilibrium state, with the $CO_2$ permeating from the interior of the membrane to the exterior of the membrane, into the surrounding tissue. The partial pressure of the $CO_2$ is then determined so as to make conclusions as to the gas in the surrounding tissue, based on the knowledge that an equilibrium state exists, as to $CO_2$ inside and outside of the balloon. The important feature of the present invention, by contrast, is to identify the content of a substance that has passed from the outside of the cuff to the interior of the cuff, so as to mix with the fluid inside of the cuff. Although in other embodiments, when the substance is intentionally added to the fluid in order to make up for an insufficient amount in the surrounding tissue, the substance obviously permeates through the membrane in both directions. In the subject matter of claim 1, however, it is important only that the analysis unit be able to measure a substance that has entered into the interior of the cuff from the exterior, due to the membrane. No such structure is disclosed or suggested in the Kruse et al reference. Although it is possible (but not explicitly mentioned) for the balloon wall in Kruse et al to be permeable to $CO_2$ in both directions in order to achieve a state of equilibrium, there is no way in the Kruse et al reference to know, and thus to measure or detect, an amount of $CO_2$ that may have entered into the interior of the balloon from the exterior. The necessity of the balloon being in an equilibrium state with regard to CO+2+ defeats even the idea of making such a measurement.

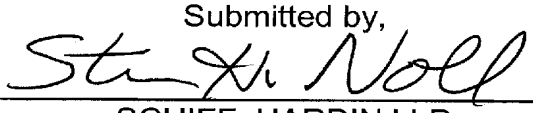
The Kruse et al reference therefore does not disclose all of the elements of claim 1 as arranged and operating in that claim, and thus does not anticipate claim 1, nor any of claims 2-5 depending therefrom.

The above arguments are also applicable to the obviousness rejections that are based on the Kruse et al reference as the primary reference. In view of these arguments, even if the Examiner is correct with regard to the teachings of the respective secondary references, the subject matter of claims 6 and 7 would not have been obvious to a person of ordinary skill in the field of designing tracheal cuffs based on the teachings of those references.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,



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